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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/050,359 03/31/98 FOWLKES

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001444 HM12/0921
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EXAMINER

PONNAI LUT, P

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/050,359

Applicant(s)
Fowlkes et al

Examiner
P. Ponnaluri

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1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 3, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 25-30, and 32-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 25-30, and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

NOTE: The change of examiner of this application.

1. The response filed on 7/3/01 has been fully considered and entered into the application.
2. Claims 22, 25-30 and 32-38 are currently pending in this application.
3. Amendment E, filed on 3/28/01 has been fully considered and entered into the application.
4. Claim 31 has been canceled by amendment E, filed on 3/28/01; claims 21 and 23 have been canceled and new claims 31-38 have been added by the amendment C, filed on 5/24/00; claims 1-20 and 24 have been canceled and new claims 25-30 have been added by the amendment B, filed on 9/29/99.
5. Claim 22 has been inadvertently not included as pending claim in the previous office action. Examiner regrets if this caused any confusion.

It is noted that in page 5 of response filed on 3/28/01, applicants have mentioned that 'claims 25-30 and 32-38 now are pending.' However, the amendment includes amended claim 22. For compact prosecution claim 22 has been examined in this application.

6. Claims 22, 25-30 and 32-38 are currently being examined in this application.
7. The INFORMATION disclosures filed on 10/21/99 have been fully considered and entered into the application.
8. The objection to the specification has been withdrawn in view of the amendments.

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9. The rejection of claims 34 (C, antecedent basis in page 6) , 35 (D in page 6 of office action) 28-29 (F, in page 7 of the office action) under 35 U.S.C. 112, second paragraph have been withdrawn in view of the arguments and amendments to the claims.

Response to Arguments

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. **Claims 22, 25-30, 32-38 are rejected under 35 U.S.C 101 and 35 U.S.C. 112, first paragraph (UTILITY) for the reasons of set forth in the previous office action mailed on 12/5/00.**

12. *Applicant's arguments filed on 3/28/01 have been fully considered but they are not persuasive.*

Applicants assertion 'that their structured panel of combinatorial peptides is useful both directly in the identification of peptides which bind targets, and indirectly, in the identification of small organic compounds which bind the same targets' has been fully considered. However, it is not persuasive because the panel of peptides are only useful in further research (that is to identify organic compounds or peptides). Thus, the research by applicants is to take place at some future time, thus the asserted utility lacks specificity.

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This is not to say that inventions that are to be used exclusively in a research setting (i.e., research tools) always lack a specific asserted utility. Indeed, many research tools such as telescopes, gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility. (See USPTO Utility Guidelines, page 12.) However, inventions that have a specifically identified utility must be distinguished from those whose utility requires further research to identify or reasonably confirm. Research tools (such as gas chromatographs, screening assays, etc.) are useful in the sense that they can be used in conjunction with other method steps to evaluate materials other than themselves or to arrive at some result. The claimed combinatorial libraries are not research tools in this sense. Rather, they are themselves the subject of basic research, whose usefulness or lack thereof has yet to be established. Merely labeling the instant libraries as "research tools" does not impart the specific utility required by this statute.

Applicants argue that the specification discloses that the panels of peptides may be used to identify non-peptide compounds that bind a target. That is the panels which contain unknown peptide sequences are used to identify non-peptides or peptides which may bind a target. In this disclosure (or interpretation), the target is unknown, and the identified non-peptide or the peptide may or may not have any utility. Further research is required to identify the peptides or non-peptides and the utility of the peptides or non-peptides. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the compounds such that another non-asserted utility would be well established for the compounds. Further, the

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compounds of the claimed libraries are not recognizable as analogous to compounds with a recognized pharmacological (or other) activity.

Applicants arguments regarding the 'real world' utility has been considered but is not persuasive. Applicants argue that peptide libraries from New England Biolabs, Invitrogen, Novagen, Display System Biotech and Stratgene are commercially available. This is not persuasive because the libraries sold are used in further research to identify specific proteins, and these libraries have defined libraries, which are different from the unstructured libraries of the instant claims. Applicants arguments that the panels are a kind of kit is not persuasive. The rejections of record have been maintained.

13. Claims 22, 25-30 are rejected under 35 U.S.C. 112, first paragraph for the reasons set forth in the previous office action (pages 4 and 5) mailed on 12/5/00.

14. Applicant's arguments filed on 3/28/01 have been fully considered but they are not persuasive. The specification does not provide a sufficient description for the claimed structured panel of library of peptides wherein the constant residue is within the middle 50 % of the sequence. The specification does not sufficiently teach plurality of libraries which are structured into a panel and the library has a constant residue which is within the middle 50 % of the sequence. The sequence in page 25, line 25 does not specifically teach that the AA (same amino acid for all the peptides in the library) is in the middle 50 % of the sequence.

15. Claims 22, 25-30, 32-38 are rejected under 35 U.S.C. 112, second paragraph for the reasons set forth in the previous office action (pages 5-7) mailed on 12/5/00.

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16. *Applicant's arguments filed on 3/28/01 have been fully considered but they are not persuasive. Applicants argue that claims 32 and 33 recite numerous inclusions and exclusions. However, the claimed peptide libraries are unstructured and have no specific recitations. The terms 'first position', 'second position' which are relative and the term 'fixed' are indefinite since the sequences and the length of the sequence are unknown. The term 'screenable' is indefinite, which would mean that 'capable of being screened' and it would be interpreted as the library is can be screened, and does not include the meaning that the library is screened.*

The term 'structured panel' is vague and rejected as not a art recognized term. The definition of the term in page 10, 'a panelthere is some structural relationship between the member libraries. But it is not clear how they are structurally related, since the length of the sequence is not known, and which would be middle residue on library may not be middle residue of another library (since the length of the peptide libraries is not constant). Thus, it is not clear what does applicants mean by the terms 'structured library' or 'fixed position'.

17. Claims 22, 25, 28-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in alternative, under 35 U.S.C. 103(a) as obvious over Pinilla et al for the reasons set forth in the previous office action mailed on 12/5/00.

These rejections over Pinilla et al have been maintained in the absence of response from applicants. The response filed on 3/28/01 does not address the rejections, thus it has been interpreted as not traversed.

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18. Claims 22, 25, 28-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in alternative, under 35 U.S.C. 103(a) as obvious over Huffman for the reasons set forth in the previous office action mailed on 12/5/00.

These rejections over Huffman have been maintained in the absence of response from applicants. The response filed on 3/28/01 does not address the rejections, thus it has been interpreted as not traversed.

19. Claims 32-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in alternative, under 35 U.S.C. 103(a) as obvious over Spatola for the reasons set forth in the previous office action mailed on 12/5/00.

Applicants argue that claim 32 requires that 'libraries of the panel collectively present a plurality of different residues at said first position'. Applicants argue that Spatola has only Asp at the fixed position. Applicants arguments are not persuasive, because the claim recites that 'first position is fixed for all libraries in the panel and is assigned the same residue for all peptides in any given library', which is interpreted as the all the libraries in the panel have same amino acid at the first position. The claim does not recite that the amino acid residue in the fixed position of each library is different. Thus, the rejections of record have been maintained.

Applicants argue that Spatola teaches cyclic peptides and the peptides of Spatola do not have middle 50 % constant aminoacid residue. Applicants arguments have been considered but are not persuasive. Since the position 'middle 50 %' is not clearly defined and the fixed amino acid residue of cyclic peptides of Spatola would not be out side the middle 50 %.

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And applicants argue that Spatola did not provide peptides by expression. This argument is not persuasive, since as pointed out by applicants in page 11 of response, claim 35 is a product-by-process claim. Since Spatola teaches peptide libraries, it does not require to teach how the product is obtained. It is obvious to one skilled in the art to make the libraries using expression vectors. The rejections of record have been maintained for the reasons of record.

20. No claims are allowed.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703)308-2439. The fax number for this group is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

P. Ponnaluri
Patent Examiner
Technology center 1600
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PADMASHRI PONNALURI
PRIMARY EXAMINER